

**REMARKS**

Claims 1-31 are in the case. Claims 23-30 are withdrawn from consideration as being non-elected in response to a restriction requirement which remains traversed. The inventions as grouped are neither independent nor distinct, each from the other, for the reasons set forth in applicants' paper of Feb. 26, 2008 and June 9, 2009. Both independence and distinctness are required for a proper restriction requirement. An article formed from a composition of Group I, as in claim 23, which is grouped separately, and a method of using the article, as in claim 29, are not separate inventions and would not even be classified differently from each other. The grounds set forth in previous Office Actions for the restriction requirement were not understood and reconsideration was requested because Groups III (claim 29) and IV (claim 30) can not be practiced without the invention of Group I. The previous Office Action said that claim 1 recites independent and chemically distinct elastomeric matrices which do not necessarily overlap in scope as further evidenced by the method for providing different chemical effects as recited in claim 29. Perhaps the examiner intended an election of species requirement rather than a restriction requirement because the grounds provided do not support a restriction requirement as applicants understand the statute, rules, precedents, and instructions in the MPEP.

The above arguments were made in the amendment filed on 9 June 2009. The restriction requirement was not repeated in the most recent October 15, 2009 2009 Official Action and so it is assumed that the restriction requirement has been withdrawn. On the other hand, the examiner has not rejected or allowed the previously non-elected claims and so it is possible that the restriction requirement has been maintained but that the examiner did not believe it was necessary to respond to the arguments in the preceding paragraph.

Claims 1-22 were previously rejected as unpatentable under 35 U.S.C. 103 over Chapin in view of Riew and Hawley's Chemical Dictionary. This rejection was withdrawn in the October 15, 2009 2009 Office Action.

Claims 1-7, 10-16, & 18-22 were previously rejected over Chapin for double patenting. This rejection was not repeated in the October 15, 2009 action and so it is assumed it was withdrawn.

Claims 2 and 6, were rejected under 35 U.S.C. 112 as being indefinite regarding the ratios. The format for the ratios and the specification as being molar has been corrected.

Claims 10-12 were rejected under 35 U.S.C. 112 as being indefinite regarding the antecedent basis for copolymer, which has been corrected to “polymer.”

Claims 1-3, 6, 10-16, and 18-22 were rejected under 35 U.S.C. 102 as being anticipated by Chapin. Anticipation requires that each and every element of the claimed invention is described in a single reference. Akzo N.V. v. United States Int'l Trade Comm'n, 808 F.2d 1471, 1479 (Fed. Cir. 1986). Anticipation is a question of fact. Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1054 (Fed. Cir. 2003). Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989) (anticipation requires that the identical invention is described in the reference). Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1554 (Fed. Cir. 1995) (same). Anticipation is a question of fact, and is reviewed accordingly. Claim 1 requires a continuous release composition comprising an elastomeric matrix which is the reaction product of a carboxyl-terminated polymer with a polycarbodiimide. Chapin fails to anticipate this claim because it does not describe one of the elements, a polycarbodiimide. Therefore claim 1 and all the claims dependent on it are novel and clearly not anticipated by Chapin. The examiner has recognized that Chapin does not disclose a polycarbodiimide, but has inferred its presence by references to other prior art, one of which, Brown '098, was not cited in any PTO-892 “Notice of References Cited.” This inference is incorrect.

Chapin is directed to compositions wherein the matrix material is polyurethane made by reaction of a polyol with a polyisocyanate. Chapin does not disclose a polycarbodiimide and so Chapin clearly fails to anticipate claim 1. The October 15, 2009 action held that “Types of polycarbodiimides used are recited (claim 13),” applicants assume the examiner was referring to claim 13 of Chapin; however, claim 13 of Chapin does not recite a

polycarbodiimide. Rather, claim 13 refers to an isocyanate, with the actual disclosure of the isocyanate component is disclosed at col. 5, line 42 to col. 6, line 8.

A polycarbodiimide is not an isocyanate and an isocyanate is not a polocarbodiimide. The official action admits that the term polycarbodiimide “is not expressly used in the teachings of Chapin,” but the “polyurethane which is formed from the reaction of Chapin in claim 1, is polycarbodiimide as defined by Torimae et al.” On the contrary, Torimae actually distinguishes urethanes from carbodiimides. See col. 2, ll. 6-15 which discloses that “[c]arbodiimide bonding takes place when isocyanate compounds are heated in the presence of a carbodiimide catalyst according to the reaction (A) \* \* \* [whereas] \* \* \*[u]rthane bonding takes place when an isocyanate is reacted with a compound having hydroxyl group according to the reaction (B) \* \* \*. If Torimae taught that a polycarbodiimide is the same as a polyurethane, it would be absolutely incorrect. Different catalysts are used to prepare each. Furthermore, applicants are not claiming a binder prepared by reacting a urethane with a polycarbodiimide but rather are claiming a binder prepared by reacting a carboxylic acid-functional polymer with a carbodiimide.

Chapin claimed the option of a carboxylic acid-terminated polybutadiene as a minor polyol component in the reaction between a hydroxyl-terminated polymer and an isocyanate to form a polyurethane. The reaction of an isocyanate and a carboxyl group leads to polyamide formation at elevated temperature, not an N-acyl urea linkage formed by the reaction of a carboxyl group and a polycarbodiimide in the claimed matrix polymer.

There is no possibility that a carbodiimide would be produced in Chapin’s polyurethane reaction, even with the presence of a carboxyl-terminated polymer as per Chapin claim 2.

In the first paragaraph on page 6 of the official action, the examiner stated that “the composition being prepared in claims 1 and 2 of Chapin is considered as reading on the composition recited by the instant base claim” and that “Chapin teaches an article comprising an elastomeric matrix and at least one active agent contained within the matrix, wherein said matrix is prepared by reacting a polyol with an an isocyanate [emphasis added]. \* \* \* Diisocyanates, such as the aforementioned, are well known in the art as being used to

produce preferred unhindered aromatic polycarbodiimides. See for example Brown et al. (USPN 3,835,089; col. 4, lines 14-40)."

On the contrary, Brown et al do not teach formation of polycarbodiimides during a polyurethane reaction, such as Chapin's, between a polyol and an isocyanate. Whether or not the polyol is, or includes a minor amount of, a carboxyl-terminated polymer, there is no reaction product between a polycarbodiimide and a carboxyl-terminated polymer possible following Chapin's disclosure and so Chapin neither anticipates nor renders obvious the claimed invention.

Since claim 1 is clearly not anticipated by Chapin, none of the claims dependent on claim 1 can be anticipated, including the claims withdrawn from consideration.

Claims 8 and 9 were rejected under 35 U.S.C. 112, 1st paragraph, as failing to comply with the written description requirement, containing subject matter not described in the specification in such a way as to convey that the inventors "had possession of the claimed invention" when they filed the application. The 1st paragraph of sec. 112 has no requirement that the inventors "had possession of the claimed invention." Said paragraph states: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Furthermore the examiner acknowledged that the term in question from claim 8, "carboxyl-terminated polyether polyols," was discussed in [0018]. The problem appears to be that no data, description, or structure has been found in the art regarding "Polyol PP 150." On the contrary, the MSDS and product data sheet for PP 150 were published well before the filing of the present application. Each of said sheets describe PP 150 in the manner required by the 1st paragraph of 112. If this response does not overcome this rejection, applicants would be willing to cancel the dependent claims upon allowance of claim 1.

Claims 1-22 & 31 were rejected under 35 U.S.C. 112, 1<sup>st</sup> paragraph, because the specification does not enable the generic class of carboxyl-terminated polymers. The term

carboxyl-terminated polymers would be well understood by those skilled in the relevant art. These polymers are but one ingredient which is reacted with another ingredient to form a matrix in which are included an active agent. The examiner has not cited any carboxyl-terminated polymers which would not be suitable in the invention but, more importantly, those skilled in the art would not intentionally use a carboxyl-terminated polymer which is unlikely to work as a matrix having the intended properties. It would be impossible for applicants to have named every single class and type of carboxyl-terminated polymer. By naming a representative sample, applicants have enabled the invention and have complied with the 1<sup>st</sup> paragraph of 112.

The Request for Information has been responded to and the requested information submitted in an earlier response.

Claims 1-22 and 31 were rejected under 35 U.S.C. 112, 1<sup>st</sup> paragraph, as not being enabled with respect to carboxyl-terminated polymers, and that only the polymers disclosed in paragraphs [0017] and [0018] are enabled. The examiner held that the ordinarily skilled practitioner would need to undergo undue experimentation “without guidance seeking from the prior art.”

According to MPEP 2164.01 Test of Enablement [R-5],

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term “undue experimentation,” it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the

invention without undue experimentation. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also United States v. Telecommunications, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Any part of the specification can support an enabling disclosure, even a background section that discusses, or even disparages, the subject matter disclosed therein. Callicrate v. Wadsworth Mfg., Inc., 427 F.3d 1361, 77 USPQ2d 1041 (Fed. Cir. 2005)(discussion of problems with a prior art feature does not mean that one of ordinary skill in the art would not know how to make and use this feature). Determining enablement is a question of law based on underlying factual findings. In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. In re Certain Limited-Charge Cell Culture Microcarriers, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

Following the guidance from the MPEP, the instant rejection should be reconsidered and withdrawn because no undue experimentation would be needed to carry out the claimed invention. As with any invention, there are theoretical embodiments within the scope which would be more difficult to carry out, and would be much less preferred and, as anyone skilled

in the art would realize, would not be suitable for their purposes. This does not mean that the claim is non-enabled.

Claims 4, 5, 8, and 9 were rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being indefinite because the term “major component” is not clearly defined. One skilled in the art would no doubt interpret said term as more than half, whereas “minor component” would be interpreted as less than half. If citation is needed, applicants can provide it.

Claims 4, 5, 8, and 9 were rejected under 35 U.S.C. 103 as being unpatentable over Chapin. Since independent claim 1 is patentable, dependent claims 4, 5, 8, and 9 would also necessarily be patentable over Chapin and so this ground of rejection need not be discussed further.

For these reasons, reconsideration of the rejections under 35 U.S.C. 112 and 102 are requested.

Claims 8, 9, and 31 were noted as being allowable if rewritten to overcome the rejections under 35 U.S.C. 112. Applicants request this indication of allowability be held in abeyance until final determination of patentability of the rest of the claims.

Respectfully submitted,

/Michael B. Fein/

Michael B. Fein  
Registration No. 25,333

COZEN O'CONNOR, P.C.  
1900 Market Street  
Philadelphia, PA 19103-3508  
(215) 665-4622 – Telephone  
(215) 701-2246 - Facsimile